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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/935,344	08/23/2001	Vic Jira	22220-00003-US	8106

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EXAMINER

LUCAS, ZACHARIAH

ART UNIT PAPER NUMBER

1648

DATE MAILED: 04/18/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/935,344	Applicant(s) JIRA ET AL.	
	Examiner Zachariah Lucas	Art Unit 1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 February 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3 and 5-16 is/are pending in the application.
- 4a) Of the above claim(s) 10-12 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3,5-9 and 13-16 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. In the prior action, mailed on August 23, 2005, claims 1 and 3-12 were pending in the application, with claims 1 and 3-9 under consideration and rejected, and claims 10-12 withdrawn as to non-elected inventions. In the Response of February 23, 2006, the Applicant amended claims 3 and 5; cancelled claim 4; and added new claims 13-16.
2. Currently, claims 1, 3, 5-9, and 13-16 are pending and under consideration.

Claim Rejections - 35 USC § 112

3. **(Prior Rejection- Withdrawn)** Claims 3-9 were rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for immunogenic compositions comprising an inactivated influenza virus, does not reasonably provide enablement for vaccine compositions, or compositions inducing immunity against, any viral pathogen. In view of the amendment of the claims such that they no longer require a protective or therapeutic effect, the rejection is withdrawn.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Art Unit: 1648

5. **(Prior Rejection- Maintained)** Claims 1 was rejected under 35 U.S.C. 103(a) as being unpatentable over Meruelo et al. (U.S. 5,506,271). The Applicant traverses this rejection on two grounds. First, the Applicant notes that the teachings of Meruelo teach the inactivation of viruses using the indicated heat treatment in combination with hypericin. The Applicant therefore concludes that those in the art would not use Meruelo's teachings of hypericin to devise the heat-inactivation method of the present invention. The Applicant's second argument is that the resulting composition of the Meruelo reference would not be formulated into a pharmaceutical composition because it causes death in the concentrations used. These arguments are not found persuasive.

The first argument is that the teachings of Meruelo teach the use of heat inactivation only in combination with hypericin treatment, and that the compositions of the reference would not use hypericin to make compositions such as those claimed. This argument is not found persuasive for two reasons. First, the present claim is drawn to any vaccine comprising a heat inactivated influenza antigen. The claims are silent as to whether any other processes have been performed in the making of the compositions. Thus, the claims are not limited to any particular treatment of the antigens so long as they have been denatured using heat in of the indicated temperature. In view of this, the fact that Meruelo uses such another treatment does not distinguish over the composition suggested by the reference.

This argument is also not found persuasive for another reason. The reference teaches that the method of inactivating influenza using hypericin may be used in combination with other modes of inactivation, such as heat inactivation. The reference therefore teaches that heat inactivation may also be performed alone to inactivate antigens that may be used to in

Art Unit: 1648

immunogenic compositions. Thus, it would have been obvious to those in the art to inactivate the influenza through the use of heat inactivation alone, as well as in combination with hypericin treatment.

The Applicant's second argument in traversal is that those of ordinary skill in the art would not use the hypericin containing compositions disclosed by Meruelo because they result in death. This argument is not found persuasive for three reasons.

First, it is noted that although the reference cited by the Applicant to teach the toxicity of the compound was not provided to the Office for consideration, and the Office was not able to access the indicated website, other teachings in the art indicate that the compound is suitable for therapeutic administration. See e.g., Miller, *Alter Med Rev* 3: 18-26 (teaching various pharmaceutical uses for hypericin); and Meruelo et al., (Meruelo II) *PNAS* 85: 5230-34 (stating in the abstract that the compound was not toxic in mice, and that this lack of toxicity extends to humans). In view of these teachings indicating that the compound may be safely administered to humans, the Applicant's arguments that it would not be used as suggested in Meruelo are not found persuasive.

Second, even if the compound was toxic, the Meruelo reference indicates that heat inactivation may be used alone. Such a composition would not comprise hypericin. The Applicant's argument is therefore also not found persuasive on this basis.

Finally, it is further noted that the reference also teaches that, in embodiments where hypericin is used to inactivate the antigen, the hypericin treatment is terminated through dilution of the hypericin, and followed by isolation and purification of the agent. See e.g., col. 7, lines 22-30. Thus, even where hypericin is used, it is not necessarily present in the administered

Art Unit: 1648

composition in amounts that would cause certain and immediate death. This is particularly the case when it is considered that the compound is administered as a therapeutic agent in at least certain low dosages.

For each of these reasons, the Applicant's arguments are not found persuasive, and the rejection is therefore maintained.

6. **(Prior Rejection- Maintained)** Claims 3-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Meruelo as applied to claim 1 above, and further in view of either of Felici et al. (U.S. 5,994,083), or Ooyama et al. (EP 0 775 494). The Applicant traverses this rejection on the same grounds presented with respect to the rejection of Meruelo above. For the same reasons as indicated above, the rejection is maintained against pending claims 3 and 5-9, and extended to new claims 14-16.

It is noted that new claim 13 additionally requires that the claimed composition comprises calcium, magnesium, or both. The Ooyama reference teaches the inclusion of various other compositions in the disclosed oral formulations. See e.g., pages 3-4. In particular, the reference teaches the inclusion of various vehicles including carboxymethyl cellulose calcium (page 3, lines 25-28), and lubricants such as magnesium stearate (page 3, lines 54-55). Similar teachings are also found in Felici, which also specifically suggests the inclusion of the lubricant magnesium stearate. Thus, the combined teachings of these references also renders obvious the composition of claim 13.

The rejection is therefore maintained against claims 3 and 5-9, and extended to new claims 13-16.

Conclusion

7. No claims are allowed.
8. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).


A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.


9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Zachariah Lucas whose telephone number is 571-272-0905. The examiner can normally be reached on Monday-Friday, 8 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 571-272-0902. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1648

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

 4/4/06
Z. Lucas
Patent Examiner

 4/15/06
JAMES HOUSEL
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